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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,278	02/20/2002	Robert E. Wagner JR.	007274-01	3427

36234 7590 06/01/2007
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EXAMINER

BAUSCH, SARAE L

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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06/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/078,278

Applicant(s)

WAGNER ET AL.

Examiner

Sarae Bausch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/26/2006 has been entered.

2. Currently, claims 56-75 are pending in the instant application. Claims 1-55 have been canceled. This action is written in response to applicant's correspondence submitted 12/26/2006.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 69 is an incomplete claim as it depends from claim 41, which is a canceled claim. Therefore, the metes and bounds of the claim are wholly unclear, and the claim is rendered indefinite.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 56-68, 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigawa in view of Wagner et al. (US Patent 6120992).

Kigawa et al. teach a method for detecting the presence of a double stranded target nucleic acid sequence using a probe/RecA complex (abstract). Kigawa et al. teach the use of a nucleic acid probe, typically a single stranded nucleic acid prepared by a virus, plasmid, or a cosmid, a probe DNA moiety excised from a vector, or probe from an oligonucleotide synthesizing method (instant claim 58) (see column 5, lines 64-67 and column 6, lines 1-10). Kigawa et al. teach probes with 90-95% homology to the target nucleic acid sequence and a length of 100 to 1500 bases but longer or short polynucleotide probe may be used (instant claim

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59) (see column 6, lines 12-18). Further, Kigawa et al. teach nucleotide probes with a label, such as a fluorescent indicator, a radioactive label or a ligand that can be bound to a specific reporter molecule such as biotin and digoxigenin (instant claim 60) (see column 6, lines 23-28). Kigawa et al. teach the use of RecA protein with a detectable label or ligand, such as a fluorescent indicator, a chemiluminescent agent, an enzymatic label, a radioactive label, biotin or digoxigenin (instant claim 61-62, 65 and 66) (see column 6, lines 61-67). Kigawa et al. teach alternatively detecting the double-stranded target nucleic acid by allowing the probe/RecA complex to react with an anti-RecA antibody with or without a label or ligand (instant claim 64 and 66) (see column 10, lines 50-58). Kigawa et al. teach the hybridization reaction can be performed in the presence of another protein, such as a single-stranded binding protein, if necessary to accelerate the reaction (instant claim 44) (see column 9, lines 18-22). Kigawa et al. teach detecting the presence of the double stranded target sequence by detecting a fluorescent signal derived from the RecA protein having a fluorescent label included in the probe/RecA complex bound to the target sequence detected with a fluorescent microscope or flow cytometer (instant claim 68-69 and 70) (see column 10, lines 24-32). Kigawa et al. teach the use of the probe/RecA hybridization method to detect various types of chromosomal aberration such as deletion and insertion (see column 13, lines 18-21). Kigawa et al. teach the use of the probe/RecA hybridization method to detect a gene containing a genetic defect (see column 13, lines 12-13). Kigawa et al. does not teach the use of MutS protein with RecA for the detection of single nucleotide base pair insertions, deletions or polymorphisms.

Wagner et al. teach the use of an immobilized mismatch binding protein, MutS for detection of mutations, polymorphisms and allele identifications (see column 6, lines 62-67).

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Wagner et al. teach allele identification by incubating detectably labeled polynucleotides with immobilized mismatch-binding protein and detecting the binding of the heteroduplex to the protein wherein the presence of the labeled polynucleotide bound to the protein is indicative of the presence of the mutation (see column 9, lines 5-38). Wagner et al. teach an immobilized mismatch binding protein can bind and detect a triplex containing a base pair mismatch (see column 22, lines 53-67). Wagner et al. teach the mismatch binding protein is attached to a solid support directly and indirectly using supports such as nitrocellulose (see column 24, lines 48-55) or avidin-biotin system (see column 25, lines 25-33) (instant claim 60, 62-64, 73-75). Wagner et al. teach genomic DNA amplified by PCR using biotinylated labeled primers (claims 57-58) (see column 59, lines 5-52 and column 53, lines 13-55). Wagner et al. teach either the probe (see column 26, lines 8-67) or the immobilized mismatch binding protein, MutS, can be labeled (see column 24, lines 29-47). Wagner et al. teach the use of MutS allows for powerful discriminatory ability and has the advantage of simplicity, accuracy, ability to be used without radioactivity, and the ability to detect all single base substitutions and mutations (see column 21, lines 10-25).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to improve the method of detecting the double stranded target nucleic acid using a probe/RecA complex by Kigawa et al. to include the MutS protein detection system of single nucleotide polymorphisms as taught by Wagner et al. to improve the method of probe/RecA detection system by Kigawa et al. The ordinary artisan would have been motivated to improve the method of detecting the double stranded target nucleic acid sequence using the probe/RecA hybridization system by Kigawa et al. with the immobilized mismatch binding protein as taught by Wagner et al. because Wagner et al. teaches that the MutS immobilized

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detection system provides a powerful discriminatory ability and has the advantage of simplicity, accuracy, ability to be used without radioactivity, and the ability to detect all single base substitutions and mutations. Furthermore, Wagner et al. teaches that the MutS immobilized system can bind and detect a triplex containing a base pair mismatch. Therefore, the ordinary artisan would have had a reasonable expectation of success that the use of MutS could be used in the be used in the method by Kigawa et al. because Kigawa teaches a method that detect triplex formation of deletions and insertion in a target DNA and Wagner teaches that using immobilized protein binding method allows for detection base pair mismatches, including base pairs in a triplex and teaches the method allows for simplicity and accuracy in of base pair mismatches.

Maintained Rejection

Claim Rejections - 35 USC § 112- New Matter

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 56-68, 70-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. This rejection was previously presented in section 7 of the previous office action mailed 07/26/2006 and is reiterated below.

Newly added claim 56 with the recitation “wherein a positive signal is generated only when two or more components are co-localized, thus allowing detection” is not supported in the specification and raises the issue of new matter. The specification teaches detecting the presence of immobilized probe DNA or RecA bound to MutS wherein the presence of the bound probe or RecA is indicative of the presence of the mutation or SNP in the test DNA (see page 6, lines 22-25) but does not mention a positive signal is generated only when two or more components are co-localized. The specification teaches that if the test DNA sequence is identical to the probe then the test is negative (see page 7, lines 15-17), however the specification does not teach generating a positive signal. Furthermore the specification teaches the most successful assay formats on page 22, lines 22-30 but does not teach that a positive signal is generated *only* when from two *or more* components are co-localized. As discussed in MPEP 2163.05, section II, the introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph.

Response to Arguments

10. The response points to numbered paragraphs within the specification for support for the claimed subject matter. However the specification submitted on 02/20/2002 does not contain paragraph numbers and upon review of the pgpub, US2004/0224336A1 there appears no reference of the cited paragraph numbers for support of the claims. Therefore, it is unclear where in the specification applicant is relying upon for support for the claimed invention.

With regard to applicants arguments that the specification does teach that one or more components must be labeled and that subsequent detection is dependent on “co-localization” of two or more components, it is noted that the specification teaches, at most, simultaneous detection of three labels (see page 19, lines 5-10). The specification does not disclose more than three labels detected simultaneously nor does the specification teach co-localization of two or more components. The claims broadly encompass positive signal detection of more than two components, which encompasses 4, 5, 6, etc components detected by a positive signal upon co-localization and the specification does not teach nor describe more than three components detected simultaneously. Furthermore, the claims encompass detecting a positive signal only when two or more components are co-localized and the specification does not teach detection of a positive signal with two or more components are co-localized. The specification only describes simultaneous detection of two (or three) labels (see page 19, lines 5-10) and does not teach that detection of a label is a positive signal. Therefore, the specification does not teach co-localization of two “or more” components nor teach that a positive signal is generated “only” when two or more components are co-localized.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

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11. Claims 56-68, 70-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigawa et al (US Patent 5965361 Oct 1999) in view of Nolan et al. (WO 99/22029 May 1999).

This rejection was previously presented in section 11 and is reiterated below.

Kigawa et al. teach a method for detecting the presence of a double stranded target nucleic acid sequence using a probe/RecA complex (abstract). Kigawa et al. teach the use of a nucleic acid probe, typically a single stranded nucleic acid prepared by a virus, plasmid, or a cosmid, a probe DNA moiety excised from a vector, or probe from an oligonucleotide synthesizing method (instant claim 58) (see column 5, lines 64-67 and column 6, lines 1-10). Kigawa et al. teach probes with 90-95% homology to the target nucleic acid sequence and a length of 100 to 1500 bases but longer or short polynucleotide probe may be used (instant claim 59) (see column 6, lines 12-18). Further, Kigawa et al. teach nucleotide probes with a label, such as a fluorescent indicator, a radioactive label or a ligand that can be bound to a specific reporter molecule such as biotin and digoxigenin (instant claim 60) (see column 6, lines 23-28). Kigawa et al. teach the use of RecA protein with a detectable label or ligand, such as a fluorescent indicator, a chemiluminescent agent, an enzymatic label, a radioactive label, biotin or digoxigenin (instant claim 61-62, 65 and 66) (see column 6, lines 61-67). Kigawa et al. teach alternatively detecting the double-stranded target nucleic acid by allowing the probe/RecA complex to react with an anti-RecA antibody with or without a label or ligand (instant claim 64 and 66) (see column 10, lines 50-58). Kigawa et al. teach the hybridization reaction can be performed in the presence of another protein, such as a single-stranded binding protein, if necessary to accelerate the reaction (instant claim 44) (see column 9, lines 18-22). Kigawa et al. teach detecting the presence of the double stranded target sequence by detecting a fluorescent signal derived from

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the RecA protein having a fluorescent label included in the probe/RecA complex bound to the target sequence detected with a fluorescent microscope or flow cytometer (instant claim 68-69 and 70) (see column 10, lines 24-32). Kigawa et al. teach the use of the probe/RecA hybridization method to detect various types of chromosomal aberration such as deletion and insertion (see column 13, lines 18-21). Kigawa et al. does not teach the use of MutS protein with RecA for the detection of single base pair insertions or deletions.

Nolan et al. teach a method of detection of DNA polymorphisms including nucleotide polymorphisms, insertions, and deletions (page 1, line 6-7) that includes using an immobilized mismatch-binding protein-coated microspheres to bind fluorescently labeled, mismatch-containing DNA by flow cytometry (instant claims 68-69) (page 4, lines 24-26). Nolan et al. teach genomic DNA amplified by PCR using fluorescently labeled nucleotide triphosphates (instant claim 57-58 and 71) (page 4, lines 26-28). Nolan et al. teach microspheres bearing immobilized mismatch-binding protein and further teach mismatch binding proteins to include bacterial mismatch-binding protein, MutS, or any other protein that recognizes DNA base pair mismatches which can be immobilized on microspheres by physical absorption or by the use of an affinity tag which binds to an affinity partner immobilized on microspheres, such as biotin affinity tag and avidin/streptavidin binding partner (instant claim 60, 62-64, 73-75) (page 5, lines 23-29 and page 6 Table).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of detecting the double stranded target nucleic acid using a probe/RecA complex by Kigawa et al. to include the MutS protein detection system as taught by Nolan et al. to improve the method of probe/RecA detection system by

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Kigawa et al. The ordinary artisan would have been motivated to improve the method of detecting the double stranded target nucleic acid sequence using the probe/RecA hybridization system by Kigawa et al. with the mismatch binding protein, MutS immobilized to microspheres taught by Nolan et al. because Nolan et al. teaches that the MutS immobilized detection system provides a high throughput, small volume, and washless method for detecting SNPs in DNA (page 4, lines 5-6). Further, the method of Nolan et al. allows for rapid scanning of mismatch DNA which would improve the detection of RecA/probe complex formation taught by Kigawa et al. The ordinary artisan would have had a reasonable expectation of success that the use of MutS could be used in the method by Kigawa et al. because Nolan et al. teach that the use of MutS immobilized onto microspheres for the detection of SNPs with flow cytometry provides multiparameter detection with excellent sensitivity in a homogenous assay format and multicolor fluorescent detection can be exploited for the simultaneous detection of dozens, or potentially hundred of analytes in a single sample (page 3, lines 9-14).

Response to Arguments

12. With regard to the applicants arguments directed to the rejections under 35 U.S.C. 103(a), all arguments have been thoroughly considered and not found persuasive.

The response that Kigawa teaches the use of RecA for determining the presence of large scale chromosomal type mutations and teaches the use of probes with at least 90 to 95% homology with the target nucleic acid. The response asserts that one of ordinary skill in the art would appreciate that such homology levels would not allow for detection of SNPs, insertions or deletions of the present invention. The response further asserts that Kigawa does not provide

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any motivation for a person of ordinary skill in the art to use MutS. This response has been thoroughly reviewed but not found persuasive.

Kigawa et al. teach detection of chromosomal aberrations such as deletion and insertions and teach the probes are *at least* 90 to 95% homologous to the target nucleic acid, which does not teach determining the presence of large-scale chromosomal type mutations (see column 6, lines 11-15 and column 12, lines 18-22). Furthermore, Kigawa et al. teach detection of specific genes (see column 12, lines 6-17) which is contrary to applicants assertion that Kigawa et al. teaches the use of RecA for determining the presence of large scale chromosomal type mutations. The reference is silent with regard to the size of the deletion and insertions that are detected within the chromosome. Furthermore, Kigawa et al. teaches the use of additional single stranded binding proteins to accelerate the reaction (see column 9, lines 18-22) which provides motivation for one of skill in the art to use additional components, more specification single stranded binding proteins to accelerate the reaction and MutS is a single stranded binding protein.

The response asserts that Nolan teaches the use of MutS for determination of small errors in single stranded DNA and does not teach labeling the MutS. It is noted that Nolan teaches the use of MutS for SNP detection (see page 5, lines 14-22 and figure 1). Therefore Nolan does not teach the use of MutS for determination of small errors in single stranded DNA but does teach the use of MutS for detection of SNP analysis. Furthermore, Nolan et al. teach MutS bound to microspheres containing affinity tag binding partners and therefore teach a labeled MutS, wherein MutS is labeled with a microspheres as well as an affinity tag (see page 5, lines 23-29).. The claims are not limited to a specific label or position of a label on MutS.

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The response asserts that there was no reasonable expectation of success that MutS would bind a triple helix structure and assert that the cited patent that teaches that MutS does bind triple helix formations teaches away from the MutS binding triplex DNA structures. The response asserts that US Patent 6120992 teaches that triplex helix structures require one non-DNA strand for binding to occur and therefore the reference provides no suggestion to binding MutS to DNA triplex structures. This response has been thoroughly reviewed but not found persuasive. '992 teaches the breadth of the ability of MutS to work with multiple different triplex formations and does not teach that it is required that one of the strands of the triplex formation must be PNA. '992 does not teach the limitation but demonstrates the breadth of the ability of MutS to bind different triplex and duplex structures. One of ordinary skill in the art would expect that MutS would bind not only the various triplex formations comprising DNA, RNA and PNA as taught in '662 but also DNA triplexes without DNA analogues. There is no teaching in '662 that MutS cannot bind a DNA triplex and therefore there is a reasonable expectation of success that MutS would bind triplex structures.

The response asserts that MutS has no interaction with RecA during repair or replication errors and asserts the function of MutS is to repair replication errors whereas RecA is a recombination protein. The response further asserts that RecA and MutS are very different to the action of both agents. The response asserts that the examiner points to no teaching in the art that suggest such systems would work with such unnatural structures. This response has been thoroughly reviewed but not found persuasive. It is noted that the examiner did not assert that RecA and MutS interact during repair or replication, but that both proteins are components or part of the mismatch repair system for E.Coli with no assertion that the proteins interact.

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Furthermore, it is noted that the examiner is not asserting that RecA and MutS function the same in vivo and in vitro, however based on the teaching in the prior art, one of ordinary skill in the art would have been motivated to use MutS with RecA for detection of mutations as '992 teaches that MutS binds triplexes, Kigawa teaches the use of single stranded binding proteins accelerate the RecA triplex formation and detection of chromosomal deletions and insertions coupled with Nolan teach the use of MutS to detection SNPs, which are encompassed by chromosomal deletions and insertions. Therefore, based on the teachings of Kigawa in view of Nolan, coupled with the evidence in the art with the teaching that MutS binds a triplex, one of skill in the art would have been motivated to use MutS with RecA to detection deletions, insertions, and SNP in a target nucleic acid.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Sarah Bausch, PhD
Examiner
Art Unit 1634
07/19/2006